

Exhibit 16

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2013-003

February 8, 2013

PROVIDING HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy regarding the respectful delivery of health care to transgender and intersex Veterans who are enrolled in the Department of Veterans Affairs (VA) health care system or are otherwise eligible for VA care.

2. BACKGROUND: In accordance with the medical benefits package (title 38 Code of Federal Regulations (CFR) section 17.38), VA provides care and treatment to Veterans that is compatible with generally accepted standards of medical practice and determined by appropriate health care professionals to promote, preserve, or restore the health of the individual.

a. VA provides health care for transgender patients, including those who present at various points on their transition from one gender to the next. This applies to all Veterans who are enrolled in VA's health care system or are otherwise eligible for VA care, including those who have had sex reassignment surgery outside of VHA, those who might be considering such surgical intervention, and those who do not wish to undergo sex reassignment surgery but self-identify as transgender. Intersex individuals may or may not have interest in changing gender or in acting in ways that are discordant with their assigned gender.

b. VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes.

c. Definitions

(1) **Sex.** Sex refers to the classification of individuals as female or male on the basis of their reproductive organs and functions.

(2) **Gender.** Gender refers to the behavioral, cultural, or psychological traits that a society associates with male and female sex.

(3) **Transgender.** Transgender is a term used to describe people whose gender identity (sense of themselves as male or female) or gender expression differs from that usually associated with their sex assigned at birth.

(a) **Transsexual (Male-to-Female).** Male-to-female (MtF) transsexuals are a subset of transgender individuals who are male sex at birth but self-identify as female and often take steps to socially or medically transition to female, including feminizing hormone therapy, electrolysis, and surgeries (e.g., vaginoplasty, breast augmentation).

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(b) Transsexual (Female-to-Male). Female-to-male (FtM) transsexuals are a subset of transgender individuals who are female sex at birth but self-identify as male and often take steps to socially or medically transition to male, including masculinizing hormone therapy and surgeries (e.g., phalloplasty, mastectomy).

(4) **Sex reassignment surgery**. Sex reassignment surgery includes any of a variety of surgical procedures (including vaginoplasty and breast augmentation in MtF transsexuals and mastectomy and phalloplasty in FtM transsexuals) done simultaneously or sequentially with the explicit goal of transitioning from one sex to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. ***NOTE:** This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.*

(5) **Gender Identity Disorder (GID)**. GID is a conflict between a person's physical sex and the gender with which the person identifies.

(6) **Intersex**. Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.

3. POLICY: It is VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender Veterans, including hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery. Sex reassignment surgery cannot be performed or funded by VA.

4. ACTION

a. **Veterans Integrated Service Network (VISN) Director**. Each VISN Director must ensure that necessary and appropriate health care is provided to all enrolled or otherwise eligible Veterans based on the Veteran's self-identified gender, regardless of sex or sex reassignment status.

b. **Medical Facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive**. The medical facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive are responsible for ensuring:

(1) Transgender patients and intersex individuals are provided all care included in VA's medical benefits package including but not limited to: hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery to the extent that the appropriate health care professional determines that the care is needed to promote, preserve or restore the health of the individual and is in accord with generally-accepted standards of medical practice.

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(a) Patients will be addressed and referred to based on their self-identified gender. Room assignments and access to any facilities for which gender is normally a consideration (e.g., restrooms) will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike. Where there are questions or concerns related to room assignments, an ethics consultation may be requested.

(b) The documented sex in the Computerized Patient Record System (CPRS) needs to be consistent with the patient's self-identified gender. In order to modify administrative data (e.g., name and sex) in CPRS, patients must provide official documentation as per VHA guidance and policy on Identity Authentication for Health Care Services and Data Quality Requirements for Identity Management and Master Patient Index Functions.

(c) Sex reassignment surgery as defined in subparagraph 2c(4), will not be provided or funded.

(d) Non-surgical, supportive care for complications of sex-reassignment surgery must be provided. For example, a MtF patient over the age of 50 may be offered breast cancer screening and may wish to discuss the benefits and harms of prostate cancer screening with her provider. A FtM transsexual patient may be offered screening for breast and cervical cancer.

(e) A diagnosis of GID, or other gender dysphoria diagnoses, is not a pre-condition for receiving care consistent with the Veteran's self-identified gender.

(2) All other health services are provided to transgender Veterans without discrimination in a manner consistent with care and management of all Veteran patients.

(3) All staff, including medical and administrative staff, are required to treat as confidential any information about a patient's transgender status or any treatment related to a patient's gender transition, unless the patient has given permission to share this information.

(4) VA Mandates diversity awareness and maintains a zero-tolerance standard for harassment of any kind.

5. REFERENCES

Title 38 CFR § 17.38 (c).

6. FOLLOW-UP RESPONSIBILITY: The Office of Patient Care Services (10P4) is responsible for the contents of this Directive. Questions related to medical care may be referred to Specialty Care Services (10P4E) at (202) 461-7120. Questions related to mental health care may be referred to the Office of Mental Health Services (10P4M) at (202) 461-7310.

7. RESCISSIONS: VHA Directive 2011-024, Providing Health Care for Transgender and Intersex Veterans, is rescinded. This VHA Directive expires February 28, 2018.

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Robert A. Petzel, M.D.
Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 2/11/2013

Attachment A

**FREQUENTLY ASKED QUESTIONS (FAQ) REGARDING THE
PROVISION OF HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS**

1. What is the prevalence of transgender individuals? Is there a difference between transgender and transsexual individuals?

a. The prevalence of transgender individuals is not known in general or in the Veteran population. This is because of challenges in defining gender identity, the reluctance of individuals to identify themselves to others as transgender, and measures that are narrowly focused on subsets of individuals who either have been diagnosed with gender identity disorder (GID) or have had sex reassignment surgery. It is for these reasons that the Institute of Medicine issued their report “The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding” (March 31, 2011) and called on Health and Human Services (HHS) and other Federal agencies to “implement a research agenda designed to advance knowledge and understanding of Lesbian, Gay, Bisexual, and Transgender (LGBT) health. This agenda includes appropriate data gathering on sexual orientation and gender identity in public health research tools and electronic health records.

b. Current estimates of the prevalence of transsexual individuals with GID are approximately 1:11,000 natal males and 1:30,000 natal females. The prevalence of all transgender individuals is much higher since “transgender” is an umbrella term that includes individuals who do not have GID.

c. Based on these data, the estimated prevalence of Male-to-Female (MtF) to Female-to-Male (FtM) transsexual individuals is approximately 3:1 in the general population. This prevalence ratio is likely to be higher in the predominantly male Veteran population. It is important to note that FtM transsexual individuals are also part of the Veteran population.

d. Intersex Veterans, that is, individuals who are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female, may or may not identify as transgender.

2. Is transgender the same as being “gay” or “lesbian?”

No. The term “transgender” refers to gender identity or the sense of oneself as male, female, or other, (e.g., androgynous, eunuch, etc.). The terms “gay” (in the case of men) and “lesbian” (in the case of women) refer to sexual orientation. The sexual orientation of gay and lesbian persons is attraction to the same gender whereas heterosexual persons are attracted to the opposite gender. A transgender Veteran may identify as heterosexual (“straight”), gay, lesbian, bisexual (i.e., attracted to both genders), queer, pansexual, asexual, etc. Knowing someone’s gender identity gives you no information about their sexual orientation.

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3. What is intersex?

Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.

4. Do all intersex individuals identify as transgender?

No. For example, an individual may be assigned the physical status of “female” at birth and identify as female throughout her lifetime, with or without knowledge of an intersex condition. Some intersex persons with male chromosomes who have been assigned female become gender dysphoric even without knowing that they were “reassigned” at, or near, birth. Knowing someone has an intersex condition gives you no information about their gender identity or sexual orientation.

5. What is sex reassignment surgery?

Sex reassignment surgery includes any of a variety of surgical procedures done simultaneously or sequentially with the explicit goal of transitioning from one gender to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or to intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.

6. Will VA provide sex reassignment surgery and plastic reconstructive surgery if needed?

VA does not provide sex reassignment surgery in VA facilities or through non-VA care. In addition, VA does not provide plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. However, patients with GID or other gender dysphoria conditions may elect to have one or more medical or surgical procedures over their lifetime to bring their bodies into a closer alignment with their perceived gender. ***NOTE:** Only a minority of transgender Veterans will undergo sex reassignment surgery, as their symptoms may often be adequately treated with other therapeutic interventions.* Some Veterans receiving care at the VA may have had sex reassignment surgery somewhere else. The VA does provide health care to pre- and post-operative transsexual Veterans, including treatment of surgical complications.

7. Will the VA provide for electrolysis through non-VA care for male-to-female transsexual (MtF) Veterans?

No. VA will not provide electrolysis as this is considered by VHA to be cosmetic rather than medically necessary to promote, preserve, or restore health of the Veteran.

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8. What are the guidelines for clinical care and the informed consent process?

a. Effective clinical care for transgender and intersex patients ideally involves an interdisciplinary, coordinated treatment approach with special attention to the needs of the individual patient and collaboration among multiple specialties, notably: gynecology, mental health, primary and specialty care, women's health, pharmacy, and urology. For all treatments and procedures, informed consent and shared decision-making needs to be the basis for individualized care that weighs the possible benefits and harms, with an emphasis on the lowest (safest) dose to achieve benefits. **NOTE:** *Procedures regarding informed consent can be found in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055.*

b. For treatment plans that include cross-sex hormone therapy, VA clinicians must, consistent with requirements of informed consent (VHA Handbook 1004.01), discuss the risks, benefits, and limitations of cross-sex hormone therapy with the patient. Signature consent is not required for cross-sex hormone therapy. Ongoing monitoring of treatment is required.

9. Will VA provide feminizing or masculinizing hormone therapy?

Yes, if it is consistent with the patient's wishes, the treatment team's clinical recommendations, and VA treatment guidance.

10. What guidance is available to clinicians regarding hormone therapy?

VA Pharmacy Benefits Management Services has developed guidance for the use of hormone therapy in transgender and intersex patients in VA. This guidance is located at: <http://vaww.national.cmop.va.gov/PBM/default.aspx>. **NOTE:** *This is an internal Web site and is not available to the public.*

11. What are the goals of cross-sex hormonal treatment? What effects and risks are associated with hormonal treatment?

a. Cross-sex hormonal treatment is used to reduce or eliminate gender dysphoria and other symptoms related to the discordance between a transgender or intersex individual's gender identity and their biological sex at birth or the gender they were assigned at birth. The treatment produces changes in hormonally-sensitive sex characteristics (i.e., reducing characteristics of the original sex and inducing those of the opposite sex). VA clinicians need to provide transgender and intersex patients with a careful evaluation prior to providing a prescription for cross-sex hormonal therapy.

b. The goal of cross-sex hormone therapy in treatment of MtF transgender patients is to suppress testosterone levels and introduce estrogen to achieve a pre-menopausal female hormonal range. The effects are decreased facial and body hair, redistribution of fat, breast development and prostate and testicular atrophy. Risks include venous thromboembolism, liver dysfunction, hypertension, and cardiovascular disease. As with any medical therapy, benefits

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and harms of treatment need individualization using principles of shared decision-making, with an emphasis upon the lowest (safest) dose to achieve benefits.

c. The goal of cross-sex hormone therapy in treatment of FtM transgender patients is to maintain testosterone and estrogen levels in the normal male range, generally through testosterone supplementation and sometimes in combination with a Gonadotropin Releasing Hormone (GnRH) agonist or progestins to suppress menses. The effects are increased facial and body hair and muscle, acne, permanent deepening of the voice, cessation of menses, redistribution of fat mass, and clitoral enlargement. Risks include hypertension, erythrocytosis, liver dysfunction, lipid changes, weight gain, and sodium retention.

12. Are there specific diagnostic criteria to consider in prescribing cross-sex hormone therapy?

a. A diagnosis of GID or other dysphoria condition should be the basis for prescription for cross-sex hormonal therapy for transgender patients. There may be clinical exceptions to the diagnosis for prescribing cross-sex hormone therapy (e.g., transgender individuals with “GID not otherwise specified”).

b. Intersex patients are excluded from the GID diagnosis by DSM IV criteria. Transgender patients with intersex conditions who are seeking hormonal treatment need to fulfill DSM IV criteria for “GID not otherwise specified.” Intersex and transgender individuals may have different mental health considerations.

13. Transgender and intersex Veterans are presenting to VA providers with prescriptions for hormones from outside sources, such as from another provider, the internet, or illicit sources. Should we stop these medications while we do a full evaluation or should a VA provider rewrite the prescriptions so they can be filled in a VA pharmacy and continued?

Under current VHA National Dual Care Policy, VA providers are not permitted to simply re-write prescriptions from an outside provider, unless the VA provider has first made a professional assessment that the prescribed medication is medically appropriate. However, cross sex hormones cannot generally be stopped abruptly without negative physical and psychiatric consequences. If the patient has records that support a thorough evaluation and psychotherapy prior to initiation of hormones, then it may be appropriate for a VA provider to rewrite the prescriptions so they can be filled in a VA pharmacy and continued while the evaluation is in progress and to monitor hormone levels. A mental health exam in this situation is not required and is based on the clinical situation. Very high doses of cross-sex hormones are associated with a greater likelihood of side effects, and a reduction in dose may be required. Additionally, the benefits and harms of hormonal therapy differ based upon the presence or absence of risk factors for, or occurrence of, serious complications (cardiovascular, thrombotic-embolic) and thus dosage needs to be individualized.

VHA DIRECTIVE 2013-003**February 8, 2013****14. What if a transgender or intersex Veteran presents to VA and self-reports that they have been taking cross sex hormones that they would like to continue but can provide no supportive documentation from a physician?**

Consistent with the VHA National Dual Care Policy, VA clinicians need to provide transgender patients with a careful medical and mental health evaluation prior to providing a prescription for cross-sex hormonal therapy.

15. Is a mental health evaluation necessary or required?

A thorough and careful mental health evaluation needs to be completed prior to provision of hormone therapy and needs to include evaluation and treatment for psychiatric comorbidities that may have overlapping presentations, such as depression, anxiety, Post Traumatic Stress Disorder (PTSD) or substance use disorders. The presence of other psychiatric and physical conditions is not necessarily a barrier to initiating treatment. For patients who enter VA with well-documented cross-sex hormone therapy from outside clinicians, mental health evaluations are optional based on the clinical presentation.

16. I understand that VA does not provide sex reassignment surgery, but are there any special considerations regarding a mental health evaluation prior to sex reassignment surgery?

Mental health evaluation prior to surgery includes specialized exams by knowledgeable doctoral level clinicians. Some professional associations with expertise on transgender issues (see resources in paragraph 28 of this Attachment) recommend that individuals contemplating genital surgery need to participate in a minimum of a 1-year “real life experience” i.e., living full time in the preferred gender role, prior to any genital surgical intervention.

17. In what ways would a pre-operative medical evaluation differ for these Veterans?

Medical evaluation prior to surgery includes pre-operative cardiac risk assessment and careful evaluation of current medications including hormone dosing.

18. What types of surgeries might transgender Veterans consider?

a. As part of their transition, FtM patients might consider undergoing several types of surgery including mastectomy, hysterectomy or oophorectomy, and neophallus construction. The common complications of neophallus construction include flap or graft necrosis, fistulae, urinary tract infection, donor site scarring, and infections. Mastectomy and hysterectomy have far fewer complications. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care.

b. As part of their transition, MtF patients might consider undergoing several types of surgery including orchiectomy, penectomy, vaginoplasty, breast implants, laryngeal shave, and facial feminization procedures. Common complications of genital surgeries include strictures,

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infections, fistulae, urinary tract complications and loss of genital sensation. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. MtF patients may consider undergoing electrolysis for hair removal. Clinicians need to be aware that VA does not provide electrolysis as this is considered a cosmetic rather than a medically necessary procedure.

19. If a patient has had sex reassignment surgery, how do we handle preventive screening requirements?

In addition to treatments related to their new gender identity, transgender patients need appropriate medical screening and/or treatment specific to their birth sex. This includes prostate exams and mammograms for MtF patients and vaginal exams and mammograms for FtM patients, as indicated.

20. Can a transgender Veteran request a change of gender or sex in Computerized Patient Record System (CPRS) before having sex reassignment surgery?

Amending the gender or sex of the Veteran in CPRS is based on the Veteran making a request to the facility Privacy Officer and providing the official documentation as required by VHA policies. Sex reassignment surgery is not a prerequisite for amendment of gender or sex in the Veteran's record.

21. What constitutes "official documentation" in order for gender or sex to be changed in CPRS?

A Veteran's request for amendment to gender or sex in the record is considered a Privacy Act "amendment request."

a. One of the following is required as supporting documentation: Legal documentation (i.e., amended birth certificate or court order), passport or a signed original statement on office letterhead, from a licensed physician. Sex reassignment surgery is not a prerequisite for amendment of gender/sex in the Veteran's record.

b. The licensed physician's statement must include all of the following information:

- (1) Physician's full name;
- (2) Medical license or certificate number;
- (3) Issuing state of medical license or certificate;
- (4) Drug Enforcement Administration (DEA) registration number assigned to the physician or comparable foreign designation, if applicable;
- (5) Address and telephone number of the physician;

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(6) Language stating that the physician has treated the patient or reviewed and evaluated the medical history of the applicant. The physician also has a doctor patient relationship with the applicant, which is evident in having one or more clinical encounters between doctor and patient;

(7) Language stating that the patient has had appropriate clinical treatment for gender transition to the new gender (specifying male or female); and

(8) Language stating, “I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.”

22. Do I need to become an expert in treating transgender Veterans?

a. All clinicians and staff who provide clinical services to transgender Veterans need to become more knowledgeable about transgender health issues. Everyone needs to be aware that transgender Veterans deserve to receive health care at VA and need to be treated with dignity and respect. Primary Care and Mental Health providers need to be encouraged to consult with specialty physicians on any aspect of management for which they need advice or for ongoing management, as they would for any other complex patient. The initial VA prescription for cross-sex hormone therapy need to be restricted to facility-designated providers experienced with the use of cross-sex hormone therapy (e.g., women’s health specialist, endocrinologist, psychiatrist, or other local designee).

b. The potential lack of clinical expertise in specialties such as endocrinology, mental health, and surgery regarding clinical care of transgender and intersex Veterans, may necessitate establishing a mechanism for timely expert consultation on complicated cases within Veterans Integrated Service Networks (VISN) or facilities.

23. What education will be provided to VA staff?

Cultural awareness and sensitivity education for field staff was developed and implemented in fiscal year 2012. The VA standard of zero tolerance for discrimination, harassment, or abuse of Veterans applies to VHA treatment of transgender and intersex Veterans.

24. What is the correct pronoun to use when speaking with a transgender Veteran and in documentation of the clinical encounter in a progress note?

Transgender Veterans should always be addressed and referred to based on their self-identified gender, in conversation and in documentation in the patient record, irrespective of the Veteran’s appearance. Neither sex reassignment surgery nor official documentation of change in sex is required for Veterans to be identified by their preferred gender or for documentation of preferred gender in the patient record.

25. Are transgender Veterans allowed to use the bathroom of their choice?

Transgender Veterans who presently self-identify as female are allowed to use bathrooms for women. Likewise, those who presently self-identify as males are allowed to use bathrooms for

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men. This is irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery. The privacy needs of other patients must also be considered; availability of "unisex" bathrooms (for men and women) throughout facilities is a practical approach to this issue and is common practice in some facilities.

26. What about room assignments?

Patient room assignments are made in accordance with the patient's self-identified gender irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery, and in consideration of the needs of other patients. ***NOTE:** Ethics consultations are encouraged when concerns arise related to the provision of respectful care for transgender and intersex Veterans and other patients.*

27. In situations where shared inpatient rooms are common, might assignments be made such that a MtF transsexual patient and a biologic female would be assigned to share a room or a FtM transsexual patient and a biologic male would be assigned to share a room?

Yes. According to current VHA policy, "room assignments will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike." Privacy and confidentiality dictate that staff may not share any information about one patient with another without express permission. If a room assignment leads to distress for either patient, then efforts need to be made to assign one of them to a private room. When this cannot be accommodated or when there are questions or concerns related to room assignments, an ethics consultation needs to be requested.

28. Are there any recommended resources for further information?

VA does not currently have clinical practice guidelines for the care of transgender and intersex Veterans. While VA does not endorse the following private sector guidelines, they may serve to provide information and education about the complexities of caring for this patient population.

a. World Professional Association for Transgender Health's Standards of Care for Gender Identity Disorders, Version 7, 2011. Available from www.WPATH.org

b. Endocrine Society Guidelines <http://www.endo-society.org/guidelines/final/upload/Endocrine-Treatment-of-Transsexual-Persons.pdf>

c. Clinical Protocol Guidelines for Transgender Care <http://www.vch.ca/transhealth> or <http://transhealth.vch.ca/resources/careguidelines.html>

d. The Joint Commission: *Advancing Effective Communication, Cultural Competence and Patient-and-Family Centered Care for the Lesbian, Gay, Bisexual and Transgender (LGBT) Community: A Field Guide*. Oak Brook, IL, Oct. 2011. <http://www.jointcommission.org/lgbt/>

29. **REFERENCES**

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c. Murad, M. H., Elamin, M. B., Garcia, M. Z., Mullan, R. J., Murad, A., Erwin, P. J., & Montori, V. M. (2010). Hormonal therapy and sex reassignment: A systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clinical Endocrinology*, 72(2), 214-231. doi:10.1111/j.1365-2265.2009.03625.x.